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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,738	11/04/2003	Brian Pope	MDX / 297	4966

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EXAMINER
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MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/700,738

Applicant(s)

POPE ET AL

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) 82-85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/19/04; 4/28/05; 1/19/06; 1/19/06; 3/9/06.

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-81, drawn to a pumping system, classified in class 604, subclass 67.
  - II. Claim 82-85, drawn to software, classified in class 700, subclass 282.
2. Inventions I and II are directed to related devices. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed do not overlap in scope and have a different design, mode of operation, and function. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.
3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Douglas Scholer on September 25, 2006 a provisional election was made without traverse to prosecute the invention of the pumping system, claims 1-81. Affirmation of this election must be made by applicant in

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replying to this Office action. Claims 82-85 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Objections***

6. Claims 11,23,30, and 66 objected to because of the following informalities: the term "window" is confusing. Examiner suggests "time interval", "time window" or "window interval". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-31, 46-67,72-74,78, and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by JHUBOO (US 5,501,665).

Regarding claims 1,13,46,55,74,78,81 Jhuboo teaches a device and a method of automatically detecting an occlusion in a fluid line of a syringe pump, the syringe pump (8) including a housing (10) adapted to support a syringe (12) containing a plunger (18) moveable inside the syringe by pushing an end of a plunger with a pusher (14) to expel fluid from an outlet of the syringe into a fluid line (tube shown in Figure 2) connected to the outlet and configured to carry the fluid under pressure to a patient, the method comprising: mounting the syringe onto the housing with the plunger end extended; coupling the pusher to the end of the plunger; initiating a pumping sequence to cause the fluid to flow into the fluid line; during the pumping sequence, using a sensor (36) to determine a first force value indicative of force in the fluid line at time T1; during the pumping sequence, determining a second force value indicative of force in the fluid line at time T2; and providing an indication of the occlusion if a relationship between the first and second force values departs from an expected relationship. Such a method is disclosed in Col 1 line 55- Col 2 line 43; the device is described in Col 2 line 67- Col 3 line 10.

Regarding claims 2,14,24 an alarm is triggered when an occlusion is detected; therefore a no-alarm condition indicates there is no occlusion

Regarding claims 3,15,57 a steady-state condition is determined (gradient constant)

Regarding claims 16-18, the gradient constant is determined from the startup time period and startup fluid volume, since the gradient constant is a function of the flow rate, or a function of volume and time.

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Regarding claims 4,19,20,22,59 a sensor (force transducer 36) is used to determine the first and second force values.

Regarding claims 5,23,48,60 a window (time interval) is determined for T1 and T2

Regarding claims 6,25,56,58,61 an expected relationship (gradient constant) is compared to the first and second force values

Regarding claims 7,8,10,26,27,29,50,52,62,63,65 a trial slope (and occlusion slope, or gradient constant) (flow rate) is determined using the first and second force values and compared to an occlusion slope

Regarding claims 9,28,47,49,51,64 the expected relationship is compared to the relationship between the first and second force values to determine if an occlusion exists.

Regarding claims 11,21,30,66 a time window is shifted to obtain an additional force value

Regarding claims 12,31,67 the indication of occlusion is cancelled when the comparison between the trial slope and the occlusion slope (or gradient constant) are compared

Regarding claims 53,54,72, and 73, a third pressure measurement after time T3 is taken to be compared to the first two measurements.

9. Claims 37-44 are rejected under 35 U.S.C. 102(e) as being anticipated by TRIBE (US 2003/0205587).

Regarding claims 37 and 40 Tribe teaches a device and a method of automatically detecting an occlusion in a fluid line of a syringe pump, the syringe pump (7) including a housing (2) adapted to support a syringe (3) containing a plunger (35) moveable inside

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the syringe by pushing an end of a plunger with a pusher (10) to expel fluid from an outlet of the syringe into a fluid line (5) connected to the outlet and configured to carry the fluid under pressure to a patient, the method comprising: mounting the syringe onto the housing with the plunger end extended; coupling the pusher to the end of the plunger; initiating a pumping sequence to cause the fluid to flow into the fluid line; during the pumping sequence, using a sensor (20) to determine a first force value indicative of force in the fluid line at time T1; and altering the flow rate in response to an occlusion. Such a method is disclosed in paragraphs 0005-0009.

Regarding claims 38,39,41-44, following indication of an occlusion, the fluid flow is reversed (reduced) for a time period until a predetermined level is reduced, then the user may manually restart the pump after the delay period.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 32,34,36,68,70,76,77 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jhuboo as applied to claims 13,55,74 and 78 above, and further in view of Tribe.

As disclosed above, Jhuboo teaches an occlusion detector where the slope of two forces over a time interval is compared to a gradient constant to determine if an



occlusion exists. Jhuboo does not discuss altering the fluid flow rate beyond the indication to the user that an occlusion exists via an alarm.

Tribe teaches that an automatic syringe pump can be controlled by an occlusion detector to reverse the flow rate and require manual restart of the pump after an occlusion has occurred (P0005-0009).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the occlusion detector of Jhuboo with the automatic fluid delivery rate controls of Tribe in order to make the pump easy to use and to prevent the user from either ignoring or failing to response to the alarm signals.

12. Claims 33,35,45,69,71,75, and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jhuboo as applied to claims 13,40,55,74 and 78 above, and further in view of MOBERG (US 6,485,465).

Regarding claims 33,35,45,69,71,75, and 79, Jhuboo teaches an occlusion detector where the slope of two forces over a time interval is compared to a gradient constant to determine if an occlusion exists. Jhuboo does not discuss the delivery of a bolus from the infusion pump, however any syringe pump is capable of bolus delivery.

Moberg teaches a infusion pump (101) and force occlusion detector (134). Moberg teaches that the occlusion detector automatically responds to force greater than the maximum allowable bolus delivery (Col 6 3<sup>rd</sup> paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the occlusion detector of Jhuboo with the bolus occlusion

detection of Moberg in order to prevent a false occlusion alarm resulting in the delivery of a prescribed bolus dose.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

*Elizabeth R. MacNeill*  
9/26/06

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SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*